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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/049,847	03/27/98	BAY S	102.166A

EXAMINER	
WESSENDORF, T	
ART UNIT	**PAPER NUMBER**
1627	16

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DATE MAILED: 01/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/049,847	Bay et al
Examiner	**Group Art Unit**
T. Wessendorf	1627

☒ Responsive to communication(s) filed on *9/28/00*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *29-47* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *29-47* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Claims 29-47 are pending in the application. Claims 1-28 have been canceled.

The disclosure is objected to because of the following informalities for reasons of record and reiterated below:

There is no Sequence Identifier No. for the sequence KLFAVWKITYKDT at page 28, lines 22 and 26. Since applicants have not assigned a Sequence ID. No. for this sequence, the objection to the disclosure is maintained. Applicants are requested to check for other sequences in the specification that have not been assigned an ID No.

It is argued that a Seq. ID is not provided for the sequence on page 28 since this is a known sequence and is not a part of applicants' invention. However, the rule requires that whether a sequence is a known or a new sequence, a sequence identifier should be assigned therein. Furthermore, even if the sequence does not form part of applicants' invention, as argued, this is immaterial, as the law requires said sequence whether it does not form part of applicants' invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The as-filed specification does not provide support for the structures as recited in the presently amended claims. The figures which contains the newly presented claims do not recite for the middle Lys residue as being of 9-13 residues as defined by the variables n and m.

The specification fails to provide a description of the structure wherein the Lys contains more than 3 residues as given in the Figures. There is no description as, for example, how the more than 3 Lys residues are linked together to form the Lys bridge.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 29 is unclear as to the attachment of the T and B to the Lys residue. Is it at the alpha or epsilon amino group? "The polylysine carrier" lacks antecedent basis from the preceding Lysine residue.

B). Claim 31 recitation of "at least 4 Tcell epitopes" is confusing since the base claim shows not more than four T cell epitopes.

C). Claim 32 is unclear as to whether galactosyl is substituted with a glycosyl residue or a substituent of galactosyl.

D). Claim 33 is confusing in the recitation of a carbohydrate being a tumor antigen, since the base claim recites for a carbohydrate being a moiety of defined structure. This claim appears to broaden the base claim.

Claims 29-47 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-14 24-29 and 33-36 of copending Application No. 09/405,986(the '986 application) for reasons of record.

Applicants' request to hold this rejection in abeyance is noted. However, since no amendments have been made to either the instant or the '986 application to clearly set forth a demarcation line between the two claimed inventions hence, the rejection is maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-47 are rejected under 35 U.S.C. 102(a) as being anticipated by Bay et al for reasons advanced in the last Office action.

It is argued that this is not a proper reference since it is not available to the public until 6/26/97 as evidenced from the submitted letter of the editor of said publication. Said letter is not evident of record. Furthermore, applicants stated that a sworn English translation of the priority application will be supplied to remove this reference. In the absence of said English translation the rejection is maintained.

Claims 29, 36-37, 39-40, 44-47 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chong et al (5,679,352) for reasons of record.

Applicants admit that Figure 1 of the Chong patent depicts several structures for the peptide carrier molecules used in the synthetic conjugates PRP-peptide and among the carrier molecules, there is described polylysine dendrimeric structures coupled to peptide antigenic determinates. Applicants continue that in lines 38-43, col. 3, it is stated that one aspect of the Chong et al concerns the enhancement of carbohydrate immunogenicity by the use of MAP type constructions containing Hib determinant as carrier molecules for the carbohydrate moiety, more precisely, the PRP carbohydrate moiety. Applicants further admit that col 5, lines 29-39 of the Chong reference encompasses the use of peptides consisting of imunodominant epitope for T-cells as PRP carriers or as autologous or heterologous B-cell epitope carriers. Nevertheless, argue that Chong does not disclose the claimed carbohydrate peptide conjugate as shown by the Formulae. However, it is considered that the structure of the conjugate of Chong would inherently, if not obviously, contain the same or similar structures as presently claimed since all the components of the conjugate of Chong is identical to the instant conjugate except arranged in structural form. Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the

PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972); In re Best 195 USPQ 430 (CCPA 1977).

It is further argued that Chong is directed to the identification of new synthetic vaccine against antigenic determinant derived from Hemophilus influenza and not to the precise structure of a peptide conjugate, as claimed. Examples 1-11 is alleged to show that Chong is interested in the chemical synthesis of the PRP and not of the carbohydrate peptide conjugate. However, applicants admit that the structure of several specific carbohydrate peptide conjugate are described by Chong.

Claims 29, 33, 36-37, 39-40, 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chong in view of Zanini et al (Bioconjugate Chemistry) for reasons advanced in the last Office action.

It is argued that Zanini's technical context is different from the technical problems solved by applicants. However, Zanini is employed for the purpose not as argued rather for the teachings of a conjugate of dendrimeric and a tumor antigen that results in the amplification of the carbohydrate antigen-protein interaction. See e.g., the abstract at page 187. Whether the problem solved by applicants is different from Zanini is immaterial to a conjugate similarly disclosed by the collective teachings of the prior art.

Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chong in view of Zanini et al as applied to claims 29, 33, 36-37, 39-40, 44-47 above, and further in view of Fung et al(Cancer Research).

It is argued that Fung does not disclose a conjugate with polylysine. However, Fung is employed to show a specific carbohydrate that has been conjugated to a carrier. Since Chong discloses broadly a carbohydrate and since Fung discloses that

specific carbohydrate as galactose has been conventionally conjugated, hence the collective teachings of the art leads one to the use of a specific carbohydrate as galactose to the carbohydrate conjugate of Chong. Since the said tumor antigen is considered to be an important human tumor marker against which an antitumor immune response could be induced, one is motivated to use said tumor antigen in the conjugate of Chong, if this is the desired tumor antigen.

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chong et al in view of Zanini and Fung and further in view of Tam [5,229,490(I) or 5,580,563(II)) for reasons of record.

It is argued that each of the Tam references are of different conception and structure. However, Tam (I) disclosure is employed for the purposes of showing that conjugates with several identical or different antigenic products of T-cell antigens and B-cell antigens joined to a dendritic polylysine would generate extremely high antibody titers as the positively disclose poliovirus, as one of the antigenic products. This advantage would motivate one having ordinary skill in the art to use T or B-cell antigens in a conjugate. Tam (II) is employed to show that a dendrimeric polylysine peptide conjugate elicits CD8+

T-cell responses against the gp 160 of HIV. Accordingly, the collective teachings of the art motivates one having ordinary skill in the art to conjugate to a polylysine carrier a T-cell or B-cell antigen and one that elicits a CD8+ T-cell response as taught by Tam I or Tam II. It would be prima facie obvious to select the type of antigen that can be attached to the polylysine as per the suggested teachings of Tam (I) that different kinds of antigen can be attached to the polylysine and provides a list of some of these antigenic determinants.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee

pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993)(see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D., can be reached on (703) 308-0570. Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

T. Wessendorf
Patent Examiner
Art Unit 1627
12/29/00